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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
03-0119 (US01)

I hereby certify that that this paper (along with any referred to as being attached or enclosed) is being transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below via the USPTO-EFS-Web filing system.

on October 16, 2007

Signature nancy Rushton

Typed or printed name Nancy Rushton

Application Number	Filed
10/674,723	09/29/2003

First Named Inventor: Harold F. Carrison

Art Unit: 3733 Examiner: David Comstock

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ Applicant/inventor.

☐ Assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☒ Attorney or agent of record. Registration number: 37,104

☐ Attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

David T Burse
Signature

David T. Burse
Typed or printed name

October 15, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 5 forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Harold F. Carrison, et al.

Serial No.: 10/674,723

Filed: September 29, 2003

For: APPARATUS AND METHODS FOR REDUCING COMPRESSION BONE FRACTURES USING HIGH STRENGTH RIBBED MEMBERS

Confirmation No.: 3995

Group Art Unit: 3764

Examiner: David Comstock

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully request a pre-appeal brief conference. No amendments are being filed with this request. Therefore, claims 1-4, 6-10 and 12-16 remain pending in this application. Claims 1-4, 6-10 and 12-16 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,193,757 to Foley et al. ("Foley"). Applicants respectfully disagree.

The Supreme Court set forth the basic test for obviousness in Graham v. John Deere, 383 U.S. 1, 148 (1966)). Additionally, the Supreme Court has recently addressed the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. (2007), in which the Court reiterated the requirement that a rejection on "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (KSR at page 14 of the slip opinion), and further that a "fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning. (KSR at page 17 of the slip

opinion). While not specifically addressed by the Supreme Court in KSR, "the prior art reference (or references when combined) must teach or suggest all the claim limitations" (MPEP §2143).

Independent claims 1 and 8 recite a device (claim 1) and a method (claim 8) for treating bone structure comprising a device with first and second members, each member having proximal and distal portions and a plurality of ribs extending from their respective distal portions, wherein the device is configured to be placed in a collapsed state by engaging the first and second plurality of ribs in an interposed arrangement, with the respective proximal portions of the first and second members spaced apart from each other, and further configured to be placed in a deployed state by disengaging the first and second plurality of ribs, with the respective proximal portions of the first and second members moved towards each other.

In contrast, Foley discloses a vertebral spacer device comprising *"a main body portion and laterally expandable portions movable coupled thereto."* (Col. 9, lines 43-49, Col. 6, lines 53-65) (Emphasis added). The device of Foley comprises a single piece having two portions or arms movable coupled to the main body portion via hinge portion located at the proximal end of the device. A tampering guide 88 protrudes from the first arm and the second arm comprises a recess 86 to receive the tampering guide 88 when the vertebral spacer is a closed position (Col. 8 lines 13-26, Figs 13-16). Even if the recess and tampering guide of Foley could be considered "ribs", Foley does not discloses that the proximal portions of the arms could moved relative to each other to collapsed (proximal portions spaced apart from each other) or to deployed the device (proximal portions moved towards each other). The final office action provides no reasoning with some rational underpinning to support the legal conclusion of obviousness over Foley regarding these structural limitations of claims 1 and 8.

By way of illustration, the embodiment of Fig. 3 of the application is compared with Fig. 15 of Foley, as follows:

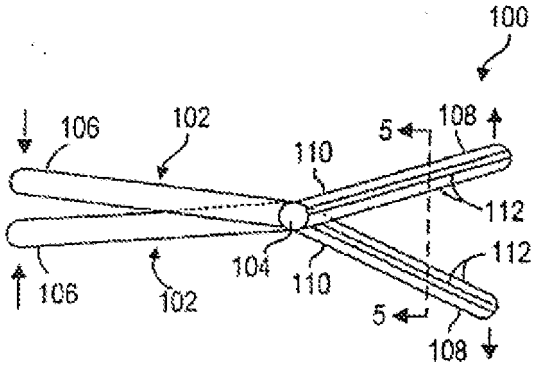

Fig. 3

US Appl. No. 10/674,723

Proximal portions 106 are movable relative to each other to collapse or deploy the device

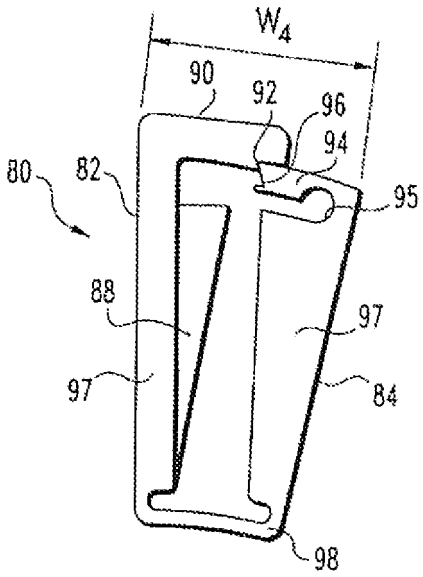

Fig. 15

USPN 6,193,757 "Foley"

Proximal portions are joined by a hinged portion, and not movable to collapse or deploy the device

Furthermore, Foley's vertebrae spacer is inserted into a vertebra in a closed position using a separate device or insertion tool operable to expand the vertebrae spacer device to its deployed configuration when the distal end of the insertion tool presses and pushes against the internal surfaces of the vertebrae spacer. The insertion tool is located through a threaded opening in the hinge portion of the vertebrae spacer of Foley. (Col. 6, line 16 to Col. 7, line 42, Col. 9, lines 15- 52). Therefore, the device disclosed in Foley is not suitable to be in a collapsed state with the proximal portions of its arms spaced apart from each other, or to be in a deployed state with the proximal portions of its arms moved adjacent to each other. Rather, Foley's device needs an insertion tool in order to expand the vertebrae spacer into a deployed configuration.

The relative positioning of the proximal portions of the arms of the Foley device plays no part on whether the device is in a collapsed or deployed configuration.

Moreover, Foley's proximal arms portions are not configured to move relative to each other, since the hinged portion of the device will not allow such movement. (See Figs. 13-16 of Foley). Certainly, Foley does not suggest that having the proximal portions of its device arms spaced apart from each other or moved toward each other would be effective to collapse or deploy the vertebrae spacer, or otherwise desirable.

A person skilled in the art would not consider modifying the device of Foley to have the proximal arms portions configured to move relative to each other, absent hindsight in view of the present application. Also, having such modification would render the Foley device inoperable for its intended purpose, since movable proximal arms extending beyond the hinged portion would interfere with insertion tool, and the arms of the insertion tool (306, 308) grab the device by the hinged portion sides, as shown in Fig. 17 of Foley.

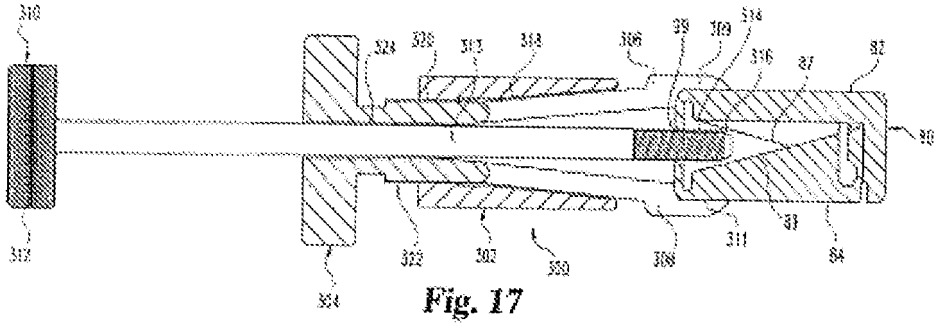

Fig. 17

USPN 6,193,757 "Foley"

Movable proximal portions extended beyond the hinge would interfere with the insertion tool, rendering the device inoperable, and the insertion tool not able to grab the device (see arms 306 and 308 griping the device by the hinge).

As such, the Examiner has not set forth a prima facie case that claims 1-4, 6-10 and 12-16 are obvious over Foley under 35 U.S.C. §103.

CONCLUSION

For the reasons set forth above, Applicants respectfully submit that currently pending claims are patentable over the cited prior art. A notice of allowance is respectfully requested.

Respectfully submitted,
VISTA IP LAW GROUP LLP

Dated: 10-15-07

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